K131576
Page 1 of 6

510(k) Summary of Safety and Effectiveness

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirement of 21 CFR Part 807.87(h).

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	May 30, 2013
Submitter:	GE Healthcare GE Healthcare (GE Medical Systems, LLC) 3000 N. Grandview Blvd., W-1140 Waukesha, WI 53188
Primary Contact Person:	Tomohiro Ito Regulatory Affairs Leader, MI&CT GE Healthcare (GE Healthcare Japan Corporation) Tel: +81-42-585-5383 e-mail: tomohiro.ito@ge.com
Secondary Contact Persons:	Helen Peng Regulatory Affairs Manager, MI&CT GE Healthcare (GE Medical Systems, LLC) Tel: 262-548-5091 Fax: 262-364-2506 e-mail: hong.peng@ge.com AUG 3 0 2013 John Jaeckle Chief Regulatory Affairs Strategist GE Healthcare Tel: 262-424-9547 Fax: 262-364-2506 e-mail: John.Jaeckle@ge.com
Product Identification:	Optima CT660
Device Trade Name:	Optima CT660
Common/Usual Name:	Computed Tomography X-ray System
Classification Names: Product Code:	Computed Tomography X-ray System per 21CFR 892.1750 90-JAK

Predicate Device	K110227 - Optima CT660
Manufacturer: /Design Location:	GE Healthcare Japan Corporation 7-127 Asahigaoka, 4-chome, Hino-shi Tokyo, 191-8503, Japan
Manufacturing location (s):	GE Healthcare Japan Corporation 7-127 Asahigaoka, 4-chome, Hino-shi Tokyo, 191-8503, Japan GE Medical Systems, LLC 3000 N. Grandview Blvd. Waukesha, WI 53188, USA GE Hangwei Medical Systems, Co, Ltd No.1, YongChang Street, Beijing Economic & Technical Development Area, Beijing PR, Beijing, 100176, China
Distributor:	GE Medical Systems, LLC 3000 N. Grandview Blvd. Waukesha, WI 53188, USA

Marketed Devices:

The Optima CT660 v2 is of comparable type and substantially equivalent to its predicate device, GE Healthcare's currently marketed Computed Tomography X-ray System Optima CT660 (K110227). In addition, the system has similar indications for use as other GE Computed Tomography X-ray Systems and identical intended use and indications as the predicate device. The system is labeled as Optima CT660. The system has completed all design controls activities including risk management, verification and validation testing per GE's quality management system and complies with the same standards as the predicate device.

Device Description:

The Optima CT660 v2 CT system is composed of a gantry, patient table, operator console, computer, power distribution unit (PDU), and interconnecting cables. The system includes image acquisition hardware, image acquisition, reconstruction software, associated accessories, and connections/interfaces to accessories.

The current system configuration/package names are: Optima CT660, Optima CT660 Pro, Optima CT660 s, Optima CT660 sPro, Optima CT660SE, Optima CT660 FREEdom.

The system generates images through the computer reconstruction of data acquired at different angles and planes of the rotating gantry. The gantry can rotate at up to 0.35 seconds per rotation, and can acquire up to 64 slices/rows of data per rotation with a

maximum total collimation coverage of 40mm in the z direction. The system can be operated in Axial, Cine, Helical, Cardiac and Gated acquisition modes.

The system is designed as an evolutionary modification to the Optima CT660 CT Scanner System (K110227). Most of hardware is identical to the predicate system, however some has undergone changes due to the need to meet IEC60601-1 Ed. 3 and RoHS regulation and also for reducing costs while maintaining performance, compliance, and specifications. The software has been updated in accordance with GE's quality management system procedures that incorporate the software development life cycle to introduce the new features discussed in this submittal. Software updates were also made for quality (bug) fixes and to meet the new requirements of IEC 60601-2-44 Ed. 3.0.

The Optima CT660 v2 uses virtually the same materials and identical operating principle as our existing marketed product, except in the case of using the compensatory ROHS compliant materials. The image chain components (tube, collimator, detector, DAS) are virtually identical to the predicate device.

The changes do not affect the intended use, the indications for use, patient population nor fundamental operating principles of the currently commercially available predicate system and are the identical or similar to other GE CT systems and features previously cleared.

The Optima CT660 v2 CT system is intended to be a head and whole body CT system incorporating the same basic fundamental operating principles and the same indications for use as the predicate device. Materials and construction are equivalent to our existing marketed products which are compliant with ES 60601-1, IEC 60601-1 and associated collateral and particular standards, 21 CFR Subchapter J, and NEMA XR-25. The accompanying documents also contain the information in support if IEC61223-3-5 and IEC61223-2-6 for acceptance and constancy testing. All changes have been tested and certified by a NRTL and continue to meet all applicable IEC/UL safety standards.

The modified system has been developed under the same GE quality system and has completed all design controls, including risk management, verification and validation.

Intended Use:

The system is intended to be used for head, whole body Computed Tomography applications.

Indications for Use:

The Optima CT660 is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes, including Axial, Cine, Helical (Volumetric), Cardiac, and Gated acquisitions. These images may be obtained either with or without contrast. This device may include signal

analysis and display equipment, patient and equipment supports, components and accessories.

This device may include data and image processing to produce images in a variety of transaxial and reformatted planes. Further the images can be post processed to produce additional imaging planes or analysis results.

The system is indicated for head, whole body, cardiac and vascular X-ray Computed Tomography applications in patients of all ages.

The device output is a valuable medical tool for the diagnosis of disease, trauma, or abnormality and for planning, guiding, and monitoring therapy.

Technology:

The Optima CT660 v2 employs the same fundamental scientific technology as its predicate device and other marketed CT systems.

The modification for this 510(k) review is the introduction of the three new optional features: Organ Dose Modulation (ODM); Ultra Kernel (UK); and High Pitch Helical (HPH).

Organ Dose Modulation
This feature enables prescription of X-Ray tube current modulation to control radiation dose to the anterior body surface where some sensitive organs such as breasts, thyroids, or eyes are located creating a virtual shield. It is a modification to our existing Automatic Exposure Control (AutomA/SmartmA) where the mA modulation now can be reduced over the user prescribed section of the rotations in consideration of more radiosensitive superficial organs/tissues..

High Pitch Helical
Enables scanning at 30.62mm/rotation or 61.25mm/rotation for 20 and 40mm collimation respectively. This feature introduces a new higher pitch helical scan acquisition parameter that meets GE's existing helical image quality specifications.

Ultra Kernel
This is a new reconstruction kernel for filtered back projection that is designed for applications where improved detail is desired.

Potential Adverse Effects on Health:

Potential electrical, mechanical and radiation hazards are identified in a risk management including hazard analysis and controlled by:

- System verification and validation to ensure performance to specifications, Federal Regulations, and user requirements.

- Adherence and certification to industry and international standards. (UL/CSA and IEC).
- Compliance to applicable CDRH 21CFR subchapter J requirements.
- Compliance to NEMA XR-25

The device is designed and manufactured under the Quality System Regulations of 21CFR820.

Determination of Substantial Equivalence:

The Optima CT660 v2 is a modified device based on the hardware and software platform of the predicate device. It was designed and is manufactured under GE's quality system that meet the Quality System Regulations of 21CFR 820 and ISO 13485. All the changes were fully verified and validated to the acceptance criteria per GE Healthcare's design control procedures under our quality system before the modified device was commercially introduced in applicable countries. In addition the Optima CT660 v2 has been successfully tested to demonstrate compliance with IEC 60601-1 (edition 3) and its associated collateral and particular standards, 21CFR Subchapter J, and NEMR XR-25. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Required Reviews
- Design Reviews
- Testing on unit level (Module Verification)
- Integration testing (System Verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

All changes were verified and validated on the bench, and the testing did not reveal any new questions of safety or effectiveness. GE believes the Optima CT660 v2 is of comparable type and substantially equivalent to our currently marketed system: Optima CT660 (K110227). The substantial equivalence was also based on software documentation for a "Moderate" level of concern device.

Summary of Additional Testing

Non-Clinical Testing
In addition to the verification and validation testing successfully completed as required by GE Healthcare's quality system, additional engineering testing was performed to provide the requisite data to substantiate performance claims, safety and efficacy, and ultimately substantial equivalence.

These tests include the objective image quality acceptance testing conducted using phantoms and performed in accordance IEC 61223-3-5 as well as the following specific tests performed on the new features:

For Organ Dose Modulation, tests on phantoms confirmed that ODM enables reducing radiation dose in the superficial tissues while maintaining diagnostic image quality. . Tests were also conducted on phantoms that confirmed the ODM enables equivalent mean CT number accuracy and uniformity.

For Ultra Kernel, phantoms were used to test and demonstrate that Ultra kernel improves visual spatial resolution while maintaining pixel noise standard deviation and level of image artifacts.

For High Helical Pitch, performance tests on phantoms were conducted and demonstrated that the helical pitch 1.531 meets GE's image quality specifications for lower pitch acquisitions.

Sample Clinical Images

47 subject clinical exams representing various acquisition modes and body regions were collected and reviewed. The exams acquired used either one or more of the 3 new features or were acquired using the system without the new features at the physician's discretion. An assessment of diagnostic quality using a 5 point Likert scale was performed by two independent radiologists.

The image quality assessment on the sample clinical CT exam images obtained on the GE Healthcare Optima CT660 2.0 scanner with the three new features demonstrated that diagnostic results (and actual diagnoses) were obtained for all 47 subject exams. This sample data was representative of a wide range of anatomical coverage and patient indications and serves to help demonstrate the modified Optima CT660 2.0 scanner with the new features continues to perform as intended and in the substantially equivalent manner to the unmodified predicate device.

Conclusion:

The Optima CT660 v2 does not raise any new potential safety risks and performs as well as devices currently on the market. Based on the conformance to standards, development under our quality system, engineering testing, and sample clinical images provided, GE Healthcare believes that the Optima CT660 v2 is as safe and effective, and performs in a substantially equivalent manner to the predicate device, Optima CT600 (K110227).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 30, 2013

GE Medical Systems, LLC
% Ms. Helen Peng
Regulatory Affairs Manager
3000 N. Grandview Blvd.
WAUKESHA WI 53188

Re: K131576
Trade/Device Name: Optima CT660 V2
Regulation Number: 21 CFR 892.1750
Regulation Name: Commuter Tomography X-ray System
Regulatory Class: Class II
Product Code: JAK
Dated: August 16, 2013
Received: August 19, 2013

Dear Ms. Peng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

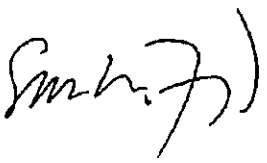
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131576

Device Name: Optima CT660 V2

Indications for Use:

The Optima CT660 is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes, including Axial, Cine, Helical (Volumetric), Cardiac, and Gated acquisitions. These images may be obtained either with or without contrast. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories.

This device may include data and image processing to produce images in a variety of transaxial and reformatted planes. Further the images can be post processed to produce additional imaging planes or analysis results.

The system is indicated for head, whole body, cardiac and vascular X-ray Computed Tomography applications in patients of all ages.

The device output is a valuable medical tool for the diagnosis of disease, trauma, or abnormality and for planning, guiding, and monitoring therapy.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) ____K131576_____